REMARKS

Claims 6–9, 23 and 25–34 are pending in this application. Claims 23, 25 and 28-31 are canceled herein without prejudice. Claims 6 and 32-34 are amended herein to point out particular features of the claimed invention so as to expedite the prosecution of the present application to allowance in accordance with the USPTO Patent Business Goals (65 Fed. Reg. 54603, September 8, 2000). Support for these amendments is found in the language of the original claims and throughout the specification, as set forth below. These amendments have been included to put this application in better condition for allowance and introduce no new matter, and Applicants respectfully request entry thereof. In light of these amendments and the following remarks, applicants respectfully request reconsideration of this application and allowance of the claims to issue.

I. Recordation of Interview Summary in accordance with M.P.E.P. § 713.04

Applicants wish to make of record the Interview Summary prepared and submitted to applicants by Examiner Kim on November 14, 2005. Applicants concur that this Interview Summary accurately reflects the substance of the telephone interview in which Examiner Kim, Examiner Horlick and applicants' representative, Dr. Mary Miller, participated. Applicants appreciate the opportunity to discuss this application and pending claims with the Examiners.

II. Rejection under 35 U.S.C. § 112, first paragraph (written description)

A. The Office Action states that the rejection of claims 6-9, 25-27, 30 and 31 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement, is maintained in the present Action for reasons of record.

As discussed during the telephone interview on November 8, 2005, claim 6 as presented herein provides an isolated nucleic acid sequence encoding: (a) a peptide immunochemically reactive with antibodies to the Epstein Barr Virus (EBV) VCA-p18 or VCA-p40 proteins, comprising an epitope of the VCA-p18 or VCA-p40 protein, encoded within the EBV open reading frames BFRF3 and BdRF1, respectively, or (b) a functional variant of said peptide

described in (a), wherein said variant is immunochemically reactive with antibodies to the Epstein Barr Virus (EBV) VCA-p18 or VCA-p40 proteins.

To address the issues discussed during the telephone interview with respect to part (a) of claim 6, applicants point out that the term "epitope" is supported in the specification on page 9, lines 1-19, as well as on page 7, lines 6-10. The term "epitope" is an art-known term that describes a region on a protein that binds an antibody. As such, an "epitope" on a protein must comprise a sufficient number of amino acids (i.e., more than one amino acid) to facilitate binding of an immunoglobulin molecule. Applicants provide herewith a printout of a page from the website www.jenobiotech.com with a generic definition of an epitope. Specifically, the printout states as follows under the heading "What is an Epitope?":

> "Antibodies are raised by the immune system against regions on the surface of a protein known as epitopes. An epitope, or antigenic determinant, is defined as a region of 6-12 amino acid or carbohydrate residues to which an antibody can bind."

The specification provides numerous examples of epitopes of the VCA-p18 and VCA-p40 proteins of this invention (e.g., in Examples 4 and 5 and Figures 4-6, as described in more detail below). Thus, the specification provides adequate written description for the nucleic acid of part (a) of claim 6.

To address the issued discussed during the interview with regard to part (b) of claim 6, as applicants' representative pointed out, the specification provides a detailed description of variants of the claimed nucleic acids on page 8, lines 3-27, including several different types of variants and examples of particular amino acid substitutions that can be employed in variants of this invention. Thus, the specification provides adequate written description of the nucleic acid of part (b) of claim 6.

In summary, as applicants pointed out in their previous response, claim 6 as presented herein defines a genus of nucleic acids that encode peptides comprising an epitope of the VCA-p18 or VCA-p40 protein of EBV or functional variants thereof, all of which are immunoreactive

with antibodies specific to VCA-p18 or VCA-p40 proteins. Thus, claim 6 is not directed to a nucleic acid that encodes any polypeptide that is reactive with any antibodies to EBV. It would be readily recognized by one of skill in the art that applicants were in possession of the genus of nucleic acids of claim 6 at the time the application was filed because the specification provides several examples of peptides comprising epitopes of this invention (e.g., SEQ ID NOs: 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 and 22; see pages 7-13 for description of peptides and fragments of this invention and Example 4 and 5, Figures 4-6 and Table 1) that are reactive with the EBV VCA-p18 or VCA-p40 proteins of this invention and also provides examples of nucleic acid sequences encoding such peptides (e.g., SEQ ID NO:1, SEQ ID NO:3.

As also discussed during the November 8, 2005 telephone interview and consistent with the comments above regarding claim 6, claims 7 and 8 as presented herein respectively encompass a specific genus of nucleic acid sequences comprising the nucleotide sequence or a subsequence of SEQ ID NO:1, wherein the subsequence encodes a peptide that comprises an epitope that is immunochemically reactive with antibodies to EBV VCA-p19 protein (claim 7), and a specific genus of nucleic acid sequences comprising the nucleotide sequence or a subsequence of SEQ ID NO:3, wherein the subsequence encodes a peptide that comprises an epitope that is immunochemically reactive with antibodies to EBV VCA-p40 protein (claim 8).

In both claims 7 and 8, the subsequence is defined as encoding a peptide comprising an epitope and thus cannot be interpreted to involve a nucleic acid that shares a single nucleotide in common with SEQ ID NO:1 or SEQ ID NO:3. It would be readily recognized by one of skill in the art that applicants were in possession of the genus of nucleic acid sequences of claims 7 and 8 at the time the application was filed because the specification provides several examples of peptides comprising epitopes of this invention (e.g., SEQ ID NOs: 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 and 22; see pages 7-13 for description of peptides and fragments of this invention and Examples 4 and 5, Figures 4-6 and Table 1) that are reactive with the EBV VCA-p18 or VCA-p40 proteins of this invention and also provides examples of nucleic acid sequences encoding such peptides (e.g., SEQ ID NO:1, SEQ ID NO:3).

Claims 9, 26 and 27 depend from claims 6, 7 and 8, respectively, and recite a vector molecule comprising the nucleic acid molecule of each respective independent claim. Because the nucleic acid sequences of claims 6, 7 and 8 are adequately described in the specification, the vectors of these claims are adequately described as well. Claims 25, 30 and 31 are canceled herein without prejudice, thereby mooting this rejection as it pertains to these claims.

At least for the reasons set forth above, applicants believe that this rejection has been overcome and its withdrawal and allowance of the pending claims are respectfully requested.

B. The Office Action states that claims 32-34 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter.

As discussed during the November 8, 2005 telephone interview, claims 32 and 33 are amended herein to delete the term "at least," thereby addressing the Examiner's issues in this regard. As also discussed in the telephone interview, the specification presents data that demonstrate that the inventors produced more than 330 12 mers of VCA-p40 and more than 160 12 mers of VCA-p18 as described in Examples 4 and 5 and as shown in Figures 4-6 and in Table 1 of the specification. Specifically, Example 4 describes the production of a full set of peptides with a length of 12 amino acids and an overlap of 11 amino acids of the amino acid sequences of both ORFs BFRF3 (VCA-p18) and BdRF1 (VCA-p40) (page 30). These peptides were assayed for immunoreactivity with EBV-specific antibodies (Example 4, page 31 and Example 5, page 33) and results of these assays are shown for the VCA-p18 peptides in Figures 4 and 5 and for the VCA-p40 peptides in Figure 6. Specifically, Figure 6 shows immunoreactivity results of almost 340 peptides of VCA-p40 and Figures 4 and 5 show such results for more than 160 peptides of VCA-p18. Thus, the peptides of claims 32 and 33 are adequately supported in the specification and no new matter is introduced in these claims.

With regard to the rejection of claim 34 as allegedly containing new matter, applicants note that the Examiner stated during the telephone interview and in the Interview Summary that this rejection of claim 34 is withdrawn upon reconsideration.

Thus, at least for the reasons set forth above, this rejection has been overcome and applicants respectfully request its withdrawal and allowance of the pending claims to issue.

III. Rejection under 35 U.S.C. § 112, first paragraph (enablement)

The Office Action states that claims 23, 28 and 29 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

As discussed during the November 8, 2005 telephone interview, claims 23, 28 and 29 are canceled herein without prejudice, thereby mooting this rejection and applicants respectfully request its withdrawal and allowance of the pending claims to issue..

IV. Rejection under 35 U.S.C. § 102(b)

The Office Action states that claims 6, 9, 23 and 25 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Ambinder et al. (1989). In particular, the Office Action maintains that the claims can be construed as being drawn to a nucleic acid encoding a peptide comprising at least part of the VCA-p18 or VCA-p40 protein, wherein the peptide is reactive with antibodies to EBV, or a functional variant of the peptide. The Examiner states that the phrase "at least part of" is given the broadest reasonable interpretation as encompassing a single amino acid residue. The Office Action then describes Ambinder et al. as disclosing a method of detecting EBV sequences in a clinical specimen by amplification involving primers and a plasmid containing EBV, which evidences the presence of a nucleic acid encoding EBV with at least one common residue with VCA-p18 or VCA-p40.

As an initial point and as noted above, claim 6 as presented herein recites nucleic acid sequences that encode a peptide comprising an epitope of the VCA-p18 or VCA-p40 protein or a functional variant thereof and thus, the nucleic acids of claim 6 can in no way be interpreted to encode a single amino acid.

As a further point, applicants' representative directed the Examiners' attention during the telephone interview to page 3,lines 2-3, wherein the "Raji" cell line of the Ambinder et al. abstract is defined as a Burkitt's lymphoma tumor cell line carrying a latent EBV strain. The specification also discloses, on page 4, lines 8-11 and lines 38-39, that proteins that are produced in latently infected cells are EBNA and LMP antigens. In contrast, the proteins of the present invention are VCA proteins, which are described on page 5, lines 8-11, as proteins that are structural components of the virus particle and are expressed late in the virus replication cycle. Thus, the nucleic acids employed in the dot blot hybridization assays described in the Ambinder et al. abstract were detecting nucleic acid encoding antigens present in a latent virus infection in cells infected with the latent Raji strain and not nucleic acid encoding VCA antigens. Therefore, it is clear that the Ambinder et al. abstract does not anticipate claim 6 or any claims dependent therefrom. For these reasons, this rejection has been overcome and applicants respectfully request its withdrawal and allowance of the pending claims to issue.

The points and concerns raised in the outstanding Office Action having been addressed in full, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested. Should the Examiner have any remaining concerns, the Examiner is invited and encouraged to contact the undersigned attorney in order to expedite the prosecution of this application.

A check in the amount of $1810.00 ($1020.00 for a three month extension of time and $790.00 as fee for a Request for Continued Examination) is enclosed. This amount is believed to be correct. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

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CERTIFICATE OF EXPRESS MAILING
"Express Mail" mailing label number: EV769243292US
Date of Deposit: December 12, 2005
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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2. Designing Antigens

The first step in the production of anti-peptide antibodies is to design the peptide antigen that will be used to generate the antibodies. To do this, the concept of an epitope and what methods are available to help in choosing the epitope must be understood.

What is an Epitope?

Antibodies are raised by the immune system against regions on the surface of a protein known as epitopes. An epitope, or antigenic determinant, is defined as a region of 6-12 amino acid or carbohydrate residues to which an antibody can bind.

There are two types of epitopes:

- continuous
- discontinuous

A continuous epitope is composed of a contiguous stretch of residues in a protein. A discontinuous epitope consists of a group of residues that are not contiguous in the sequence, but are brought together by the folding of the polypeptide chain, or by the juxtaposition of two separate peptide chains. Figure 5 shows examples of a continuous epitope and a discontinuous epitope.

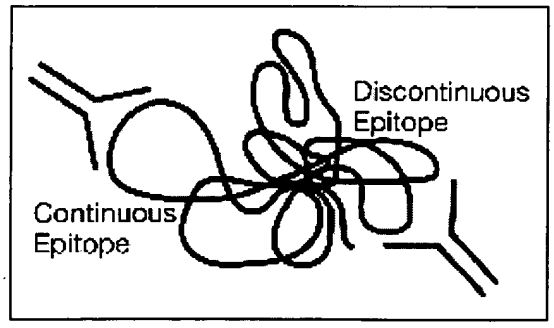

Figure 5. Continuous and discontinuous epitopes